IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

NEBRASKA BEEF, LTD.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,

Defendant.

CASE NO. 8:03CV16

FILED
DISTRICT OF NEBRASKA
AT 10:50 P. M.
JAN 14 2003
Gary D McFarland, Clerk
Deputy

John F. Bataillon Judge

PLAINTIFF'S COMPLAINT, APPLICATION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION

Plaintiff, Nebraska Beef, Ltd. ("Nebraska Beef"), files this Complaint, Application for Temporary Restraining Order, Preliminary Injunction, and Permanent Injunction ("the Complaint") against the United States Department of Agriculture ("the USDA"), and, in support thereof, would respectfully show the Court the following:

Emergency Nature of the Relief Requested

The USDA, with less than twenty-four (24) hours notice and with no opportunity for hearing, has effectively shut down the operations of Nebraska Beef's business by ordering the withdrawal of its Federal meat inspectors. As a result, approximately 1,100 Nebraska Beef employees cannot work and customer orders cannot be met. Nebraska Beef is a major supplier of beef for this, and other, Districts, and its ability to maintain its business is at stake as a result of the USDA's action. Nebraska Beef respectfully requests

this Court treat this Application as an emergency, deserving of immediate Judicial intervention under Fed.R.Civ.P. 65.

Parties

1. Nebraska Beef is a Nebraska Corporation with its principal place of business in Omaha, Nebraska.

2. The USDA is an instrumentality and agency of the United States of America. The USDA may be served herein, pursuant to Rule 4(i)(a) of the Federal Rules of Civil Procedure, by delivering a copy of the Summons and this Complaint to: (1) the United States Attorney for the District of Nebraska or to an Assistant United States Attorney or clerk or employee designated by the Unites States Attorney in a writing filed with the Clerk of this Court or by sending a copy of the Summons and of the Complaint by registered or certified mail addressed to the Civil Process Clerk at the Office of the United States Attorney; (2) by also sending a copy of the Summons and the Complaint by registered or certified mail to the Attorney General of the United States at Washington, District of Columbia; and (3) by also sending a copy of the Summons and the Complaint by registered or certified mail to the USDA.

Jurisdiction and Venue

3. This Court has original jurisdiction of this case under 28 U.S.C. § 1331 because this is a civil action arising under the Constitution, laws, or treaties of the United States. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims contained herein occurred, or a substantial part of the property that is the subject of this action is situated in, the District of Nebraska.

Facts

4. The Federal Meat Inspection Act, 21 U.S.C.S. §§ 601, et seq., directs the Secretary of Agriculture ("Secretary") to cause the inspection of meat packing plants; to prescribe rules and regulations of sanitation under which such establishments shall be maintained and where the sanitary conditions are such that the meat or meat food products are rendered adulterated to refuse to allow the meat products to be marked, stamped, or tagged as "inspected and passed". 21 U.S.C. §608.

5. In addition, the Secretary has the power to appoint inspectors to examine cattle, the carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which meat and meat products are prepared, and directs the inspectors to refuse to stamp, mark or tag any such product until the product is inspected and found not to be adulterated. 21 U.S.C. § 621.

6. In July of 1996, the USDA created what it called the Hazard Analysis and Critical Control Point ("HACCP") system. The USDA enacted 9 C.F.R. § 417.2 to require a meat packing plant such as Nebraska Beef to conduct a Hazard Analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the prevented measures the plant can apply to control those hazards. In addition, plants such as Nebraska Beef were required to develop and implement a written HACCP plan covering each product produced by that plant whenever a hazard analysis revealed one or more food safety hazards that were reasonably likely to occur based on the hazard analysis referenced above.

9 C.F.R. § 500.4, as adopted, provides that the Food Safety and Inspection Service ("FSIS") may impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve

compliance with regulations if their HACCP system is inadequate as defined in 9 C.F.R. § 417.6 due to multiple or recurring non-compliances. In addition, 9 C.F.R. § 500.4 provides that FSIS may impose a suspension if the Sanitary Standard Operating Procedures ("SSOP") have not been properly implemented or maintained.

9 C.F.R. § 500.4 further provides that the FSIS may institute a suspension if the establishment does not maintain sanitary conditions as prescribed in § 416.2-416.8 due to multiple or recurring non-compliances.

9 C.F.R. § 500.5 provides that in the event FSIS suspends inspection and does not hold the suspension action in abeyance as provided elsewhere in the section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 C.F.R. Subtitle A, Part 1, Subpart H, at which time the administrator will file a complaint which will include a request for an expedited hearing.

9 C.F.R. § 500.6 provides that the FSIS administrator may file a complaint to withdraw a grant of federal inspection in accordance with the Uniform Rules of Practice, 7 C.F.R. Subtitle A, part 1, subpart H.

7. Nebraska Beef is a meat packing and processing plant that has operated in Nebraska since October, 1995. As a major part of its business operations, Nebraska Beef slaughters and processes, on the average, 2,200 beef cattle per day. Its primary end product is boxed beef which it sells to supermarkets in numerous states. A byproduct of its boxed beef operation is "trimmings", the remnants from the boxed beef which it sells to processors who process the trimmings into ground beef. Nebraska Beef sells this product to major retailers, the government and others. Throughout its history, no consumer death or illness related to tainted beef has been attributed to any product processed and/or packed by Nebraska Beef.

8. Nebraska Beef has a long history of working and cooperating with the USDA. For many years the USDA, through FSIS and Agricultural Marketing Service, has conducted inspections to insure that Nebraska Beef is complying with federally mandated procedures regarding sanitation and conducting business in a way that provides for unadulterated product being distributed to the public for consumption.

9. Throughout Nebraska Beef's existence as a meat producer, the USDA has tested samples of Nebraska Beef's product for adulterants[1], and Nebraska Beef has likewise conducted its own testing program for adulterants and pathogens alongside the USDA.

10. On August 30, 2002, Nebraska Beef was informed that the USDA was going to conduct an assessment of Nebraska Beef's facilities and operations. The USDA stated that it determined an assessment was necessary solely because Nebraska Beef had been identified as a supplier of beef trimmings to All American Meats. All American Meats had been identified by the USDA as the sole supplier of product found to be adulterated with *Escherichia coli* ("E. coli"). However, All American Meats was not the sole supplier of the product in question and when confronted with this fact, the USDA quickly changed its story as to why it deemed an assessment of Nebraska Beef facilities was necessary.

11. On Friday, September 6, 2002, at 6:30 p.m., the USDA, through its agent, the Food Safety and Inspection Service ("FSIS"), notified Nebraska Beef of the USDA's "consideration to suspend the assignment of FSIS inspection personnel for all operations at Establishment 19336, Nebraska Beef Ltd., Omaha, Nebraska . . .." *See* Exhibit 1, the September 6, 2002,

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[1] "Adulterant" is a term of art defined in the National Meat Inspection Act, 21 U.S.C. § 601(m).

Notice of Intended Enforcement Action ("NOIA"). This consideration was based on what the USDA called "findings from a comprehensive public health investigation by a team of FSIS subject matter experts . . ." which took place the week of September 2, 2002. *See* Exhibit 1. The investigation was purportedly "in response to the identity of Nebraska Beef as one of a few suppliers of meat products used to prepare ground beef which was identified by FSIS to contain pathogenic *Escherchia coli 0157:H7* [(*E. coli*)]." *See* Exhibit 1. There was no evidence that Nebraska Beef had produced any product adulterated with *E. coli*.

12. The September 6, 2002, suspension was based on certain alleged deficiencies in Nebraska Beef's HACCP and SSOP, which the plant implemented pursuant to federal regulations. If the plant fails to maintain a HACCP plan, the USDA will immediately suspend the assignment of FSIS inspection personnel. Therefore, the USDA effectively requires a HACCP plan from Nebraska Beef. By withdrawing the inspectors, Nebraska Beef is effectively prohibited from continuing its operations and fulfilling its commitments to its customers, resulting in roughly $2,700,000.00 in lost revenues daily and the loss of employment to 1,100 employees.

13. The specific findings set forth in the NOIA are found in Exhibit 1. In general, there were three areas of criticism:

A. The Hazard Analysis and Critical Control Point system ("HACCP") at Nebraska Beef allegedly failed to meet Title 9, Part 417.6;

B. The Sanitation Standard Operating Procedure ("SSOP") allegedly had not been properly implemented or maintained pursuant to Parts 416.13 through 416.16; and

C. An alleged failure to maintain sanitary conditions as prescribed in 9 CFR 416.2.

14. Upon receipt of the NOIA, Nebraska Beef immediately took action. Although it was too late to stop production on Saturday, September 7, 2002, employees, consultants and counsel reviewed the NOIA assigned tasks and, on Saturday, September 7, 2002, began the work of responding to the NOIA. As reflected in the attached Affidavits, the Nebraska Beef employees and consultants worked, in effect, around the clock in responding to the NOIA while, at the same time, remedying many of the alleged inadequacies, setting forth remedial actions and demonstrating why the USDA should not determine the Nebraska Beef HACCP system was inadequate or that its SSOP was not in regulatory compliance.

15. Nebraska Beef, on September 10, 2002, requested an extension to respond to the NOIA. This request was denied on September 10, 2002 (Exhibit 2), despite the USDA having granted an extension to All American Meats, one of the customers of Nebraska Beef, for a substantially shorter NOIA received by All American Meats less than two weeks earlier.

16. In its response to the NOIA, Nebraska Beef set forth numerous actions it had taken to remedy the alleged inadequacies in its HACCP and SSOP, as well as committing to numerous additional actions.

17. On September 13, 2002, the USDA provided plaintiff with oral notification that plaintiff's response to the NOIA was inadequate to avoid a suspension of production activities and that it was suspending production activities at plaintiff's facility effective immediately.

18. On September 14, 2002, the USDA followed up the oral notification referenced in paragraph 17 above with written notification which stated that "[t]he suspension will remain in effect until you provide this office

with meaningful documentation we can recognize as demonstrative that your operations will be in compliance with regulations relevant to your operations." *See* Exhibit 3.

19. On September 15, 2002, Nebraska Beef again responded to USDA concerns in a seven page correspondence detailing numerous additional changes to be made to its operations, as well as clarifying previous changes to which it committed, in an attempt to have the suspension of inspection services lifted, thereby allowing production to resume. *See* Exhibit 4.

20. On September 16, 2002, Nebraska Beef followed up its September 15, 2002 response with a one page clarification on two issues which required the Agency granting Nebraska Beef 30 days to collect scientific data. *See* Exhibit 5.

21. Also on September 16, 2002, representatives of the USDA and representatives of Nebraska Beef participated in a conference call. During the conference call, Agency representatives informed Nebraska Beef that FSIS would hold the suspension of inspector assignment in abeyance thereby allowing production operations to resume. The production was to be performed under Nebraska Beef's revised SSOP in the Slaughter and Fabrication HACCP plans.

22. On September 17, 2002, the USDA issued Nebraska Beef a written "Notice of Suspension Held In Abeyance" which reiterated the Agency's decision allowing Nebraska Beef to resume production operations. *See* Exhibit 6.

23. During the intermittent time from September 6, 2002, to September 17, 2002, Nebraska Beef was subject to an increased level of scrutiny of its production operations. Agency inspectors issued numerous

Non-Compliance Reports ("NR's") to Nebraska Beef for allegedly unsanitary conditions and various other alleged violations of USDA regulations. Many of these same conditions were previously present in Nebraska Beef facilities without incident or complaint or NR activity from Agency inspectors. *See* Exhibits 7 and 8. Furthermore, and most telling, other packing plants which operate under the supervision of the USDA FSIS office in the Des Moines, Iowa District, do not receive NR's for similar conduct. *See* Exhibit 8. On September 19, 2002, Nebraska Beef informed the Agency of the effect this new level of scrutiny was having on business operations.

24. Despite having knowledge of the effect the increased, arbitrary and capricious treatment had upon Nebraska Beef's operations, such treatment continued and continues to date, culminating in the latest threat to withdraw inspection services from the plant.

Claims for Relief

A. FIRST CAUSE OF ACTION

THE USDA'S ACTIONS IN CARRYING OUT ITS STATUTORY DUTIES TO PROVIDE MEAT INSPECTION SERVICES TO NEBRASKA BEEF AND ITS DECISIONS TO SUSPEND INSPECTION SERVICES ARE ARBITRARY AND CAPRICIOUS IN LIGHT OF PLAINTIFF'S THOROUGH RESPONSE TO THE USDA'S NOTICE OF INTENDED ENFORCEMENT ACTION AND PLAINTIFF'S CONTINUED COMPLIANCE WITH APPLICABLE LAW

25. Plaintiff incorporates paragraphs 1-24 as though set forth fully herein.

26. In response the USDA's September 6, 2002, Notice of Intended Enforcement Action letter, Nebraska Beef provided the USDA with an eleven page reply letter on September 11, 2002. Nebraska Beef's reply letter detailed numerous ways in which the company planned to address the alleged deficiencies noted in the USDA's September 6, 2002, letter.

27. Under the applicable C.F.R. provisions, the USDA had the option of granting Nebraska Beef a deferment or abeyance of the enforcement action, thereby allowing Nebraska Beef to continue its operations while remedying the perceived deficiencies.

28. Nonetheless, the USDA declined to allow deference or abeyance to Nebraska Beef. Doing so was an arbitrary and capricious decision which was not rationally related to the furtherance of the goals of the FMIA.

29. Furthermore, the increased level of scrutiny with which the USDA has carried out its inspection duties at the Nebraska Beef plant were, and are, arbitrary and capricious in light of Nebraska Beef's continued compliance with applicable regulations and laws.

B. SECOND CAUSE OF ACTION

THE USDA'S FAILURE TO OFFER A HEARING BEFORE SUSPENDING SERVICES IS ARBITRARY AND CAPRICIOUS AND VIOLATES PLAINTIFF'S CONSTITUTIONAL DUE PROCESS RIGHTS

30. Plaintiff incorporates paragraphs 1-30 as though set forth fully herein.

31. The decision to suspend inspection services deprives Nebraska Beef of its property without Due Process required by United States Constitution. Prior to suspending its inspection services the USDA did not allow Nebraska Beef an opportunity for a formal hearing on the merits of the decision.

32. The USDA's failure to provide Nebraska Beef the opportunity for a formal hearing prior to withdrawing its inspection services is arbitrary and capricious and not rationally related to the goals of the FMIA and violates Plaintiff's Constitutional Due Process Rights.

C. THIRD CAUSE OF ACTION

THE USDA REQUIREMENT THAT NEBRASKA BEEF MAINTAIN HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS ("HACCP")PLANS AND STANDARD SANITATION OPERATING PROCEDURES ("SSOP") PLANS IS ULTRA VIRES TO THE AUTHORITY GIVEN THE USDA BY CONGRESS IN THE FEDERAL MEAT INSPECTION ACT ("FMIA")

33. Plaintiff incorporates paragraphs 1-32 as though set forth fully herein.

34. The USDA requires Nebraska Beef to maintain HACCP plans and SSOP plans for its plant operations. The USDA allegedly is acting under it authority pursuant to the Federal Meat Inspection Act ("FMIA") 21 U.S.C. § 601 et. seq.

35. The FMIA does not authorize the USDA to make such a requirement of Nebraska Beef or any other meat packing plant.

D. FOURTH CAUSE OF ACTION

ASSUMING THAT THE USDA'S HACCP AND SSOP PLANS ARE NOT ULTRA VIRES TO FMIA, THE USDA SUSPENDING INSPECTION SERVICES AS A RESULT OF A FAILED HACCP OR SSOP PLAN IS ULTRA VIRES TO THE FMIA

36. Plaintiff incorporates paragraphs 1-35 as though set forth fully herein.

37. Even if this Court finds that the FMIA does grant the USDA authority to require a HACCP plan, under the FMIA the USDA has limited authority to remove its inspectors from a packing facility.

38. The FMIA does not grant the USDA authority to withdraw its inspectors for any alleged deficiencies in a HACCP or SSOP plan.

Application for Temporary Restraining Order, Preliminary Injunction and Permanent Injunction.

39. The allegations contained in paragraphs 1-38 are incorporated herein by reference.

40. This application is supported by the Affidavits attached hereto. *See* Exhibits 7-14.

41. For the reasons described above, immediate and irreparable injury, loss or damage will result to Nebraska Beef for which it will have no adequate remedy if a temporary restraining order is not issued immediately to restrain and enjoin the USDA from suspending inspections services at the Nebraska Beef plant. In this regard, Nebraska Beef would show that without inspection services, Nebraska Beef and its approximately 1,100 employees cannot sell or supply ground beef to its customers. Ground beef is a perishable product that is shipped to customers on a daily basis. Without inspection services for as little as one (1) to two (2) days, Nebraska Beef's customers will be forced to find alternate supplies product, and they may be lost as Nebraska Beef customers forever. *See* Exhibits 12 and 13.

42. A substantial likelihood exists that Nebraska Beef will prevail on the merits of its claims herein. The issuance of a temporary restraining order and preliminary injunction will result in absolutely no harm to the USDA. Finally, because Nebraska Beef has *never* been found to produce adulterated product of any kind, the public will in no way be harmed by the issuance of a temporary restraining order or preliminary injunction.

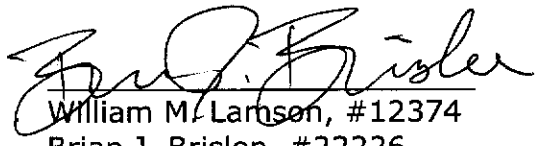
43. Accordingly, Nebraska Beef respectfully requests this Court, *ex parte* and without notice, enter a temporary restraining order enjoining the USDA from withdrawing inspection services to Nebraska Beef. After notice of a hearing, Nebraska Beef requests that such temporary restraining order be

continued as a preliminary injunction and, ultimately, as a permanent injunction.

WHEREFORE, Nebraska Beef respectfully requests that this Court, *ex parte* and without notice, enter a Temporary Restraining Order enjoining the USDA from withdrawing inspection services to Nebraska Beef. After notice and hearing, Nebraska Beef requests such temporary restraining order be continued as a preliminary injunction, and, ultimately, as a permanent injunction. Nebraska Beef further requests that the Court enter a declaratory judgment as more fully described herein. Finally, Nebraska Beef respectfully requests that the Court grant such other and further relief to which it may show itself justly entitled.

DATED this 14th day of January, 2003.

NEBRASKA BEEF, LTD., Plaintiff,

By: 

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State of Nebraska)
Douglas County) ss

William Hughes

Subscribed & sworn to before me this 14th day of January, 2003

Sharon K. Koch

United States Department of Agriculture
Food Safety and Inspection Service
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309
Phone: 515-727-8960

September 6, 2002

FAX – FOLLOWED
BY U.S. CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Nebraska Beef Ltd.
Establishment 19336
Attn: William Hughes, President
4501 South 36th Street
Omaha, Nebraska 68107

Dear Mr. Hughes,

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our consideration to suspend the assignment of FSIS inspection personnel for all operations at Establishment 19336, Nebraska Beef Ltd., Omaha, Nebraska (Nebraska Beef.). This notice and the consideration to take such an enforcement action are based on findings from a comprehensive public health investigation by a team of FSIS subject matter experts during the week of September 2, 2002. The assessment was conducted in response to the identity of Nebraska Beef as one of a few suppliers of meat products used to prepare ground beef which was identified by FSIS to contain pathogenic *Escherchia coli* 0157:H7.

Specific findings are described below, but in general, the Hazard Analysis and Critical Control Point (HACCP) system at Nebraska Beef is inadequate as defined under Title 9, Part 417.6 due to multiple noncompliances. Further, the Sanitation Standard Operating Procedure (SSOP) has not been properly implemented or maintained as specified in Parts 416.13 through 416.16. Also, Nebraska Beef has not maintained sanitary conditions as prescribed in 9 CFR 416.2 through 416.6. Our representatives discussed the findings of our public health investigation with you and/or your representatives today.

SANITATION PERFORMANCE STANDARDS

Specific to the findings of noncompliance under Parts 416.2 through 416.6, among other things, these regulations require that rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions. Our FSIS representatives observed inedible material being conveyed to the outside through an edible product room, where inedible material was seen dropping off the belt into a traffic area where uncovered combo bins of edible products were freely moving.

EXHIBIT
tabbies
1

Further, these regulations require ventilation to be adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary. Your Standard Sanitation Operating Procedures (SSOP) indicate that the company allows condensation to form. Our representatives observed a problem in several areas related to condensation and direct product contamination. Your establishment records provided no indication that the company was actively trying to control the condensation, or that the condensation does not constitute a food safety risk even if the surfaces from which the condensation falls are cleaned and sanitized daily.

Also, these regulations provide that water, ice, and solutions used to chill or wash raw product may be re-used for the same purpose, provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Nebraska Beef uses a Chad Hot Water Pasteurizing System in the slaughter department that recirculates water. However, there was no documentation provided to indicate that the establishment was meeting this performance standard. The company failed to produce microbiological records when requested, although they indicated that they had some records generated after documentation of noncompliance by in-plant FSIS personnel in October and November 2001. Nebraska Beef is not currently performing any microbiological testing on the recirculated water used in this system.

Under 9 CFR 416.4, all food-contact surfaces, including food-contact surfaces of utensils and equipment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product. Our representatives observed numerous incidences where knives being used in the slaughter operations were not being adequately sanitized to meet this sanitation performance standard.

Further, Part 416.4 specifies that product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments. Our representatives observed the offal freezer with heavy ice accumulation and direct product adulteration of exposed product in this freezer by pallets and boxes touching the product. FSIS in-plant inspection personnel had recently taken an official control action in this freezer where the reject tag was removed without authorization. Exposed product was observed in this freezer. Damaged and broken boxes of product were also present in this freezer. Upon entering the freezer, personnel and product must enter through the plastic curtain flaps. The curtains had condensation and other debris present. The exposed product would have come in contact with the curtains.

Under 9 CFR 416.5, all persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions. However, our representatives observed that during wash down at the lunchtime, employee implements such as aprons and gloves were hung on several rails or stands. Our representatives could not confirm the prevention of cross-contamination from the wash down. FSIS representatives observed that

when some of the employees returned for work, their aprons still had blood and other debris present and they did not clean off their aprons. Further, FSIS representatives observed a liquid dripping from an overhead unit in the packaging room of the manufacturing of variety meats.

Under 9 CFR 416.6, when an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary, or that its use could cause the adulteration of product he/she will attach a U.S. Rejected tag to it. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a U.S. Rejected tag. As indicated above, there is documentation on file of a recent incident in which the establishment removed such a reject tag.

SSOP

The following information reflects findings that lead to the conclusion that the Nebraska Beef SSOP has not been properly implemented or maintained as specified in Parts 416.13 through 416.16. The establishment's records provide no indication that they routinely evaluate the effectiveness of the SSOP and the procedures therein in preventing direct contamination or adulteration of products, and that they revise both as necessary to keep them effective and current with respect to changes in facilities or equipment.

PRE-OPERATIONAL SANITATION

Our FSIS representatives observed establishment personnel performing a Pre-operational Sanitation procedure on September 4, 2002, at approximately 0450 hours. SSOP records documenting the deviations and corrective actions described below were not provided as requested upon leaving the plant the following day on September 5, 2002 at approximately 1630 hours. The following deviations were observed.

FABRICATION

- A liquid that appeared to be condensation from overhead air return ducts was dripping on product contact surfaces of production lines I and II.
- Follow-up clean-up employee, with the Quality Control Technician performing Pre-operational Sanitation, was using a solution from an unidentified bucket to scrub product contact surfaces. The solution was stated to be white oil (mineral oil).

SLAUGHTER

- Stainless Steel Buckets (edible) were staged in various areas of the kill floor, inside of these buckets were paint chips and black grease specks.
- An overhead airline had a hole in the bottom, evidenced with rust surrounding the hole and dripping fluid. This airline was directly over the carcass chain area.
- The inside of pipes for the hot water pasteurization unit were not smooth finishes. Further, the QC personnel who were performing the inspection did not look beneath and/or between equipment, nor was there any evidence that the monitoring techniques used were adequate to detect insanitary conditions.

OFFAL ROOM (approximately 0530 to 0630 hours)

- The plant QA Technician had identified unacceptable condition on approximately two dozen pieces of equipment. On each piece of equipment, a QA Hold Tag was placed, however the identification of this equipment and the deviation identified was not recorded on the tag. The corresponding tag number of the tag was not removed. The Plant Manager, Mario Villerreal, was following the QA Technician writing down the pieces of equipment that were being tagged.
- Overhead condensation, heavily beaded with some dripping, had not been removed prior to the company performing their pre-operational sanitation.
- The clean-up personnel spot scrubbed areas with scrub pads, using a solution from buckets that had no identification as to what chemical was being used. Other areas were only rinsed or no obvious corrective action was performed. This is not following the written corrective action outlined in the SSOP plan that was provided to our public health representatives.

At approximately 0630 hours, the offal room was presented to the assigned FSIS Inspector as ready for pre-operational inspection. However,

- Overhead condensation had not been removed. The clean-up personnel had been notified to remove the condensation and began to do so with floor squeegees. The clean-up supervisor then halted the process and made them wash the squeegees and wrap them with paper towels to remove the condensation. During the process of removing the condensation, drops of condensation repeatedly dropped onto product contact surfaces. The offal department was then presented to the FSIS Inspector for reinspection. At this time, the equipment had not been re-cleaned or sanitized after the dripping condensation had contaminated the product contact surfaces.
- After the equipment had been re-cleaned, the FSIS Inspector was informed of paint droplets adhered to product contact surfaces of two product chutes. Overhead areas were continuously dripping, under which the company hung plastic as a temporary corrective action in addition to removing the paint.
- A separate issue was identified to the FSIS Inspector for corrective action prior to the start of production where a liquid was continuously dripping from a seam and a cut opening of a wrapping on an overhead pipe. The company only wiped the pipe wrapping, without performing a corrective action to prevent further dripping from the unknown source of the liquid. The FSIS Inspector was instructed to take further regulatory control action and document this issue on a separate Noncompliance Record for procedure code 06D01. Further dripping during production would have resulted in the water dripping from above an edible product line directly onto edible product moving on the line. The FSIS Inspector released this area at approximately 0730 hours.

OPERATIONAL SANITATION

During operations of the fabrication department at the lunch break, edible barrels and inedible barrels were allowed to touch each other without the establishment taking corrective action. Also, frocks were being hung over inedible barrels (touching) while the employees were taking a lunch break. The assigned FSIS Inspector was notified and took a regulatory control action.

Plant records indicate that operational sanitation monitoring is an ongoing procedure throughout the production day, and that employees will identify deficiencies and take corrective actions.

During the initial plant familiarization tour in the carcass chilling coolers, numerous necks of beef carcasses were observed to have partial neck wounds (knife entry damage from bleeding) and heavy clotting of blood inside of the necks. The outside of some carcasses indicated that they lacked an adequate washing process and/or intervention to remove any other residue on the carcasses. On the kill floor, there was evidence of side sticking of the beef carcasses after carcasses splitting. The washing of these stick wounds was not being adequately performed (pressure of the carcass wash was turned down to a point that there was no washing effect). After the carcasses passed through the carcass wash cabinet, the flank meat was dropped approximately 12 inches creating an overlap onto a lower portion of the hindquarter. A portion of several vertebras of the neck bone was hot boned and allowed to overlap the lower portion of the neck. These necks drug on approximately a 20 foot section of cutting board. This process was not depicted on the Slaughter Flow Chart or on the Hazard Analysis for the Slaughter HACCP plan. It was not likely to allow for the following interventions of hot water pasteurization or lactic acid spray to adequately contact these over-lapped areas of the carcass. Later in the day, at approximately 1345 hours the red muscle portion of the beef carcass necks had a scorched appearance (white surface) as if the hot water pasteurization was partially cooking the muscle tissue of the carcasses.

SLAUGHTER/ANTEMORTEM AREAS

Our representatives observed a plant employee hosing down some of the live cattle and questioned the practice. Our representative was told that the reason for the hosing practice was to decrease the amount of dust that comes into the plant. FSIS observed that not all cattle were hosed. The plant was not following their supporting documentation to support this practice. Additionally, our representatives observed an employee place his booted foot on the hide of one carcass in order to turn the carcass around. On the slaughter floor, the screened windows were open allowing street dirt and dust to enter the slaughter floor. Further, this air from outside was blown by large fans over the offal table after the location where FSIS inspectors were performing inspections.

FABRICATION ROOM

Condensation was present on a drip-pan with an open container of product beneath it. The inspection team questioned the deficiency and was told that Nebraska Beef had a sanitation program in their SSOP that stated that the surface was sanitized prior to production.

HACCP

Specific to the findings relative to the determination that your HACCP system is inadequate as defined under Title 9, Part 417.6 are described below.

Contrary to requirements of 9 CFR 417.2, our representatives determined that your establishment does not address all the steps in your processes, and fails to address food safety hazards at these steps. A flow chart describing the steps of each process and product flow in the establishment is required, and the intended use or consumers of the finished product shall be identified.

Your establishment failed to validate your HACCP plans adequacies in controlling food safety hazards identified during the hazard analysis, and to verify that the plans are being effectively implemented. The establishment failed upon initial validation to conduct activities designed to determine that the HACCP plans are functioning as intended. No evidence was provided to our representatives that the establishment routinely reviews the records routinely generated by the HACCP system in the context of other validation activities. These conditions do not comply with 9 CFR 417.4

Ongoing verification activities for the calibration of thermometers were not being properly performed. Thermometers from Fabrication and Slaughter departments are calibrated in the QC office. QC personnel perform this randomly at a frequency of no less than one a week. The media of crushed ice in water and boiling water are used to calibrate thermometers for near freezing and near boiling temperature monitoring, respectively. No action is documented when the variance is above a limit.

The QC individual performing the verification and recording the results did not know the manufacturers specifications for the thermometers. Thermometers with variance are adjusted at that time. The procedure outlined by the plant does not follow the data included in the HACCP plan to support thermometer calibration. The plant procedure does not indicate if distilled water is being used or how long the thermometer is left in the boiling water or ice bath. The document says the probes cannot touch the side of the vessel, but the team observed the probes touching the sides of the vessels. Additional documentation requires a NIST certified instrument but none is utilized.

The other thermometer calibration material included information from Kansas State University that the plant is not following. The thermometer calibration log documents numerous occasions where the thermometers were found out of calibration. However, no corrective action was taken except to recalibrate the thermometer. No documentation was reviewed to see the effect on the product as a result of the finding while performing this verification activity.

Slaughter HACCP Plan
The Slaughter HACCP plan does not include the hot boning procedure or tenderizing. The Fabrication HACCP plan does not include a process step for reworking of carcasses which may be retained on the slaughter floor for lead shot, or a hazard analysis. Again, this does not comply with 9 CFR 417.2.

Regulations in 9 CFR 417.5 require that each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry. Further, that prior to shipping product, the establishment shall review the records associated with the production of that product to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s). The Slaughter HACCP plan Preshipment Review does not meet these requirements. Plant records indicate that multiple entries are being made on the HACCP records with no time indicated for the specific monitoring event.

Your firm was not able to provide our representatives with any pre-shipment review forms to confirm the effectiveness of your Slaughter CCP during their visit. Plant management indicated verbally that there were records, but none were provided until the exit conference. Our representatives were not able to effectively evaluate your slaughter pre-shipment records at that time. Your managers did provide offal pre-shipment records.

Further, your establishment has failed to maintain the necessary supporting documents for the establishment's HACCP plan as required under 9 CFR 417.5. Specifically, in the Slaughter HACCP plan Slaughter CCP 1 established a fecal contamination prevention critical control point with monitoring procedures described as a visual inspection of 5 carcasses per hour. The basis for the selection of your critical limit at this CCP is a Generic *Escherchia. coli* testing production rate of 1 per 300 head slaughtered. The 5 head per hour selection is based on production averaging 275 head per hour. There is no identified relationship by the plant in regards to the regulation of Generic *Escherchia. coli* to the visual inspection.

Your hazard analysis indicates a biological hazard and that the establishment must meet the regulatory requirement to remove visible contamination. The generic *Escherchia. coli* regulation is an objective process control indicator for fecal contamination only, not all contamination in the slaughter process. The basis for the selection of 1/300 is related to data collected from the National baseline, however this selected frequency is not associated with in-plant validation of data to support the incidence of the contamination found in this establishment. There is no data to support the selected location and frequency of monitoring for this CCP.

There is also no supporting documentation for the development of this critical limit. Team observations indicated that the monitoring of this CCP is not adequate as performed due to the speed of the line and the monitoring required by the plant to be effective as designed to prevent, eliminate, or reduce fecal contamination. Our representatives observed the monitoring personnel having difficulty in performing the assessment of the carcasses in the time allowed. This is further affirmed by your in-plant inspection records that indicate multiple recurring noncompliance with zero tolerance.

Nebraska Beef 8.

Considering your Slaughter CCP 2 for lactic acid spray of carcasses, Nebraska Beef uses a journal article on *Validation of Acid Washes as CCP in Hazard Analysis and CCP systems.* Dormedy, Bashears, Cutter, and Burson Journal of Food Protection Vol 63. No. 12, 2000 Pages 1676 – 1680. This article indicates the lactic acid concentration needs to be at 2% to be most effective. However, the plant does not follow this specific procedure in the article.

The critical limit is a range as opposed to a minimum or maximum value and fails to meet the definition for a critical limit. On the average, the establishment utilizes a concentration of 1.5% lactic acid spray. However, there is no in-plant data available to support and validate the lactic acid wash at this concentration level as an effective intervention step in the slaughter process. The article indicates that water pressure and the nozzle function must be monitored. This is not part of the monitoring of the CCP but is monitored by the plant as a control point. The article indicates that organic acid washes do not offer a magic bullet for the industry to eliminate pathogenic hazards, but that they are only effective in reducing the initial microbial load on the carcass. This is not a substitution for a strict sanitation program and good manufacturing practices.

A second journal article on *Microbiological Decontamination of Food Animal Carcasses by Washing and Sanitizing Systems: A Review* by Dickson, and Anderson Journal of Food Protection Vol. 55 No. 2 Pages 133-140, indicates good manufacturing practices are important in preventing food safety hazards from microbial growth. Our FSIS representative's observation of sanitation indicated a problem meeting the Sanitation performance standards and SSOP requirements as indicated above. The establishment had the manufacture's recommended use as part of their supporting documentation. The Purac spray lactic acid carcass decontamination information indicates that the carcasses should not be washed after application of lactic acid, and that the higher the concentration - up to 2.5%, the more effective the spray.

The lactic acid system should also be used prior to chilling, according to documentation described earlier, and if it is used after cooling, the antimicrobial effect is not as potent. The company has a documented problem with carcasses falling off the rail transport system. Part of reconditioning the chilled carcass is the application of lactic acid spray after reconditioning the carcass, which is not consistent with the recommended use by the manufacturer. The FSIS representatives observed that the top spray nozzle for the Lactic Acid did not appear to effectively spray the upper quadrant of the hindquarter, and could not determine that effective application of this lactic acid system is made on larger cattle passing through the system. On the hot boned carcasses, large portions of muscles were folded over, prohibiting the lactic acid spray from being applied to these inside surfaces.

For the Slaughter CCP 3 - Chilling of carcasses. The establishment has not adequately designed or executed the monitoring of this CCP. Nebraska Beef has no records to support that they meet the critical limit for this CCP for every production day. Specifically, where slaughter operations occurred on a Saturday, monitoring activities should be documented on Sunday to show the

temperature had been met within 24 hours, but were not. This time/temperature relationship was established to control a food safety hazard in their food safety system. There is no documentation that the company evaluated hot spots in the cooler. The team observed the selection of carcasses for temperature monitoring, which was from the areas in the cooler where the most air circulated to cool the carcasses most effectively. Carcasses in potentially warmer locations in the cooler were selected for monitoring.

For the Slaughter CCP 4B - Chilling of variety meats. The establishment has no means of determining when the 24 hour period specified as part of their critical limit has occurred. The thermometer calibration log indicated the thermometer used to monitor this CCP was not properly calibrated, and there was no follow-up action related to the last acceptable check of the thermometer which occurred the prior week.

Fabrication HACCP Plan

The Fabrication HACCP plan Critical Control Point 1 B for surface temperature monitoring of the carcass at the time of breaking and cut-up or fabrication has no decision-making or supporting documentation regarding the selection of the critical limit or of the monitoring frequency. This apparent absence does not comply with 9 CFR 417.5

Nebraska Beef failed to take corrective action required under 9 CFR 417.3 in response to a deviation from a critical limit for Critical Control Point 2B. Specifically, the critical limit of an average room temperature of less than 50°F was not met on July 19, 2002. The average temperature that was recorded was 50.75°F. There were no corrective actions documented. The record was verified by Lola Morales on July 20, 2002 at 9:28AM. The pre-shipment review was signed and dated also.

Also for CCP 2B, there is no supporting documentation to confirm validation for the selection of the critical limit, or of the frequency of every two hours. The establishment has no method to identify affected product in case of a deviation. The monitoring of this CCP was performed at approximately the same time every day at a 2 hour interval. All 4 temperatures were recorded at the same time. When observed, the temperatures are observed and verified in a sequence with several minutes between each observation. There was not a system in place to provide randomness of taking the room temperature. The critical limit for this CCP is the average of the 4 temperatures not to exceed 50°F. There are no validation or decision-making documents to support this as an effective critical limit. Thermometers in the Fabrication process were not identified to correlate calibration with the calibration log. The temperature sensing portion of the thermometers were touching the metal bracket holding them, likely giving a faulty reading of air temperature. The temperatures were an average of three separate rooms, a vestibule in the carcass cooler, the fabrication room, and a separate room used to prepare specialty products for export. The pre-shipment was signed at the same 2 hour interval when the carcass and room temperatures were monitored and verified.

A letter on file in the government office states that the product coding system used by this establishment consists of a shipping date placed on the boxes prior to loading on a trailer, and a sequential number printed on the product labels. There is a different series for each product produced and is only found on the preprinted labels. Labels printed by Nebraska Beef do not have this sequential numbering printed on them. This numbering system is only for tracking production dates, and in not put on the HACCP records to correlate with the pre-shipment records and times. This number coding system does not allow for rework product and cannot provide an accurate tracing of product produced, or accurately indicate which pre-shipment review form may relate to the product.

Micro Testing for Escherchia coli 0157:H7

Nebraska Beef utilizes an organic acid intervention step in their slaughter process. There is currently no in-house data to indicate that the intervention is effective. The establishment, at customer's request, provides documentation that the intervention step has been validated by *Escherchia. coli* O157:H7 testing. There is not any mention of this testing in the hazard analysis or HACCP plan. The establishment performs the screening test for this pathogen at the Nebraska Beef in-house laboratory. Available records show that all samples have tested negative. By your program, if a presumptive sample is obtained the sample will be sent to a contract laboratory for confirmation. The method used by the establishment (Eclipse by Ephrogen) has not been AOAC approved. No documentation to support this method's equivalency to an approved method was provided to the FSIS representatives when requested.

The establishment uses the specific enrichment procedure for Medi^{TM} accelerated 9 - 10 hour growth medium, which calls for incubation at 40-42°C for 9-10 hours. The instructions stated that incubation at a lower temperature might result in false negatives. The technician stated that they are incubating the samples at 37°C that calls in to question the validity of the test results. The procedure for dealing with a presumptive positive is not documented. Company representatives indicated they have no specific policy, and there was no written policy in place related to the volume of product that might be held in the event of a presumptive positive sample.

The establishment only provided the team with limited documentation to support Slaughter CCP numbers 3 and 4, and Fabrication CCP numbers 1 & 2. The documentation consisted of a National Association of Meat Processors, Science Letter dated January 19, 1999, from James L. Marsden, Regents Distinguished Professor of Meat Science. The letter indicates that it must be validated at the establishment, but there is no data to support or validate these CCPs. The company indicated that they have data from the University of Nebraska representing data collected at the plant, but they did not produce the data to support this claim, and this data was not included in the supporting documentation when the team requested all supporting documentation and decision-making documents for the hazard analysis and HACCP plan.

Nebraska Beef

GENERIC ESCHERCHIA COLI TESTING

Nebraska Beef is failing to meet 9 CFR 310.25 that requires the recording of test results. The establishment is not maintaining accurate records of all test results, in terms of CFU/cm\2\ of surface area sponged.

Our public health representatives observed the sampling procedures in use at Nebraska Beef. They determined that the method of carcass sampling did not follow FSIS guidelines. Specifically, the carcasses were moving and touching other carcasses, the ladder, and the technician as he attempted to swab the carcasses. The chart depicting the results of the generic *Escherchia coli* testing shows a baseline of 20 CFU/cm^2. This upper control limit was derived from an unspecified industry study that was not provided to our representatives for review. The generic values reported ranged from 0-9 CFU/cm^2. This value is below the baseline of 20 CFU/cm^2. The record of the results did not indicate the unit. The dilution factor was not considered, resulting in incorrect interpretation of the data collected. The establishment also failed to develop criteria for their generic *Escherchia coli* testing by performing their own baseline study, using in-house data to establish upper control limits and statistical process control charts.

As provided in Part 500.4, FSIS may impose a suspension after providing prior notification that your HACCP system is inadequate, that your SSOP has not been properly implemented or maintained, and that your establishment has not maintained sanitary conditions, which we have done above and through our representatives today. Part 500.5(b) provides you the right to contact this office to contest the basis for the proposed action, or to explain how compliance has been or will be achieved. Before we implement the suspension, we are affording you the opportunity to demonstrate why a HACCP system inadequacy determination should not be made, or why we should not make a determination that your SSOP has not been properly implemented or maintained, or further that you have achieved regulatory compliance.

Please provide this office a written response within three (3) working days from the date of this letter. We will expect your reply by 4:00PM on September 11, 2002. We will determine any further action based on your response. If you have any questions regarding this matter, please contact Donald Ehlers at 515-240-5884.

Sincerely,

for Dennis E. Greening
District Manager
Des Moines District

United States Department of Agriculture

Food Safety and Inspection Service

Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309
Phone: 515-727-8960

September 10, 2002

FAX DELIVERY ONLY

Nebraska Beef Ltd.
Establishment 19336
Attn: William Hughes, President
4501 South 36th Street
Omaha, Nebraska 68107

Re: Request for Extension of Time to File Response, dated September 9, 2002.

Dear Mr. Hughes,

This office is in receipt of your written request for an extension of time to respond to our Notice of Intended Enforcement dated September 6, 2002. Our records indicate that your firm received the Notice at approximately 6:30PM on September 6, 2002. The Notice was hand delivered by FSIS Consumer Safety Officer Donald Ehlers.

Regulations in 9 CFR 500.5(b)(5) provide that FSIS must advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS. Our Notice established the time limit for your response as 4:00PM on September 11, 2002.

Your request did not provide an adequate description of specific actions you have already taken in order for this office to decide favorably on your request. Additionally, we are aware that your firm worked on Saturday, September 7, 2002. We did not include that production or business day in establishing the current time limit

Therefore, your request for an extension of time is denied. You may appeal this decision under 9 CFR 306.5 to the Associate Deputy Administrator for FSIS, Office of Field Operations by phone at (202) 720-3697, or fax at (202) 720-6050.

Sincerely,

Dennis E. Greening
District Manager
Des Moines District

EXHIBIT
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United States Department of Agriculture
Food Safety and Inspection Service
Des Moines District Office
210 Walnut Street, Suite 985
Des Moines, IA 50309
Phone: 515-727-8960

September 14, 2002

FAX – FOLLOWED
BY U.S. CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Nebraska Beef Ltd.
Establishment 19336
Attn: William Hughes, President
4501 South 36th Street
Omaha, Nebraska 68107

NOTICE OF SUSPENSION TO REMAIN IN EFFECT

Dear Mr. Hughes,

This letter confirms oral notification of the suspension of inspection at Establishment 19336, Nebraska Beef Ltd. (Nebraska Beef), Omaha, Nebraska that was provided to you at approximately 6:15PM on September 13, 2002, by Martin Hickman, Assistant District Manager for Enforcement. As you were informed at that time, the suspension was effective immediately.

The suspension applies to all operations conducted under your Sanitation Standard Operating Procedure (SSOP) as well as those under your Hazard Analysis and Critical Control Point (HACCP) plans for Slaughter and Fabrication, and is based on the following.

On September 6, 2002, this office provided your firm with a Notice of Intended Enforcement (NOIE). The NOIE served as official notification by the United States Department of Agriculture, Food Safety and Inspection Service (FSIS) of our consideration to withhold the marks of inspection and suspend the assignment of inspectors for all operations conducted at Nebraska Beef. This consideration was based on the findings of a comprehensive public health assessment during the week of September 2, 2002.

As stated in the NOIE, the assessment was conducted in response to the identity of Nebraska Beef as one of a few suppliers of meat products used to prepare ground beef that was identified by FSIS to contain pathogenic *Escherchia coli* 0157:H7.

To restate the basis of our consideration to take such enforcement action, FSIS determined that your HACCP food safety system at Nebraska Beef is inadequate as defined under Title 9, Part 417.6 due to multiple noncompliance. Further, the SSOP has not been properly implemented or maintained as specified in Parts 416.13 through 416.16. Also, Nebraska Beef has not maintained sanitary conditions as prescribed in 9 CFR 416.2 through 416.6.

EXHIBIT
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On September 11 and 13, 2002, Nebraska Beef provided this office with written responses to the Notice of Intended Enforcement. On September 13, 2002, a teleconference call was established between FSIS representatives, you, and your Establishment representatives to discuss the efficacy of your response toward establishing regulatory compliance with food safety regulations. Our FSIS representatives on the call advised you that your responses failed to demonstrate why an inadequate SSOP and HACCP system determination should not be made, or that you had achieved regulatory compliance.

The suspension will remain in effect until you provide this office with meaningful documentation we can recognize as demonstrative that your operations will be in compliance with regulations relevant to your operations. In order for this office to consider allowing the assignment of FSIS inspection personnel to resume, you must at a minimum address the following concerns.

VAPOR BARRIERS

This office has not received plans that demonstrate your ability to control condensation at Nebraska Beef. As you know, 9 CFR 416.2(d) requires ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions. Continued demonstration of your inability or unwillingness to control condensation is accentuated by the documentation of problematic condensation by in-plant FSIS personnel after the FSIS public health investigation during the week of September 2nd, and after you received the Notice of Intended Enforcement on September 6, 2002. In-plant inspection personnel documented condensation findings since the earlier date on Noncompliance Record numbers 57, 61, 62, 71, and 83 dated September 4, 5, 5, 9, and 13, 2002, respectively.

Your SSOP indicates that the company allows condensation to form. As evidenced above, FSIS representatives have observed problems in several areas related to condensation and direct product contamination. Your response to our Notice provides inadequate affirmation that the company will actively try to control the condensation, or that the condensation does not constitute a food safety risk. This office recognizes the plant improvements you plan to make in air handling as constructive toward controlling condensation. However, your Pre-operational Sanitation plans offer no remedy for product contact surfaces that may have become contaminated during the removal of condensation in step B8 before your Pre-operation sanitation inspection. Regarding your Operational Sanitation, specifically article B3, your plans failed to specify the frequency with which each ***procedure*** in the SSOP is to be conducted. The documentation of condensation under your article B3 does not establish a procedure your designated individual is to follow in order to control condensation. Lastly, you and your representatives were not able to tell us in conference on September 13th, on what basis you elected to monitor for condensation plant wide at a frequency of once per hour. Plans you have submitted to date fail to demonstrate that your operation will be in compliance with, among others, 9 CFR 416.12.

Additionally, plans you have submitted to date fail to demonstrate that your operation will be in compliance with, among others, 9 CFR 416.2. Specific to the use of your Chad Hot Water Pasteurization System, the document you submitted as Attachment 4 of your response to the NOIE is reflective of industry data demonstrative of this systems' ability to comply with 9 CFR 416.2(g)(3). However, the documents you submitted as Attachment 5 failed to demonstrate required plant specific data to use the system in compliance, because your data contains no control values for comparison to show control of microorganisms. Hence, your plant specific data does not establish compliance with Part 416.2(g)(3).

Further regarding this Chad Hot Water system, you indicated in your response dated September 11th, that you will commence microbial testing the week of September 16, 2002, in a specific manner. While the plant specific data you submitted as described above does not tell you that the proliferation of microorganism is controlled, it does appear to tell you that there are microbial hazards present in the circulated solution that poses a hazard to product moving through the system. This leads FSIS to examine your Hazard Analysis for this step in the process. The Hazard Analysis you submitted as Attachment 2 on September 11th, for Step 19 (for hot water pasteurization) indicated "Yes" to the question, "Is the potential food safety hazard significant?" However, you provide no decision-making documents revealing your justification to not control this apparent hazard with the selection and development of a Critical Control Point. Hence, FSIS has determined that the plans you have submitted to date fail to demonstrate that your operation will be in compliance with, among others, 9 CFR 417.5.

Regarding your Slaughter CCP-2B Kill, you and your representatives elected to change the Critical Limit for lactic acid concentration from the range of 1.0% to 2.5% as described on your CCP Description, Critical Limits, Monitoring Procedures, Corrective Action chart to an actual Critical Limit value of 2.5%. However, your plans do not consider other parameters vital to controlling microbial hazards with this decontamination system that are expressed in the manufacturers specifications. During conference on September 13th, you did not amend your plans when you were informed that without inclusion of all specification parameters, or in lieu of that, your decision-making documentation to justify controls without all or some of the specification parameters, FSIS could not determine that your plans would provide for operations in compliance with 9 CFR 417.2 and 417.5. The parameters you had not included were determinations that the delivery nozzles were functioning properly, maintenance of a prescribed pressure of 20-40psi, and maintenance of specified delivery temperature.

Also, during the conference, you and your representatives were informed that use of a lactic acid solution in excess of a 2.5% concentration requires concurrence from FSIS that, among other things, such use does not produce a residual effect on the product. You were informed that you could call our FSIS Technical Services Center at 1-800-233-3935 for information about how to submit your request on this subject. Your September 11th cover letter alludes to your intent to use a 4% concentration solution of lactic acid solution as partial means of reconditioning chilled carcasses that have fallen to the floor in handling.